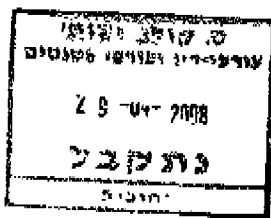


PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To:
SANFORD T. COLB
SANFORD T. COLB & CO.
P.O. BOX 2273
REHOVOT, ISRAEL 76122



PCT

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference
35828

Date of mailing
(day/month/year)

FOR FURTHER ACTION See paragraphs 1 and 4 below

International application No.
PCT/IL05/00849

International filing date
(day/month/year) 08 August 2005 (08.08.2005)

Applicant
SMART MEDICAL SYSTEMS, LTD.

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
1211 Geneva 20, Switzerland, Facsimile No.: (41-22) 338.82.70.

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.
3. ☐ With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:
- ☐ the protest together with the decision hereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
 - ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. Reminders

Shortly after the expiration of 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within 19 months from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later); otherwise, the applicant must, within 20 months from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of 30 months (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/US
Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
Facsimile No. (571) 273-3201

Authorized officer

Linda C.M. Dvorak

Telephone No. 703-308-2193

Form PCT/ISA/220 (January 2004)

(See notes on accompanying sheet)

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To:
SANFORD T. COLB
SANFORD T. COLB & CO.
P.O. BOX 2273
REHOVOT, ISRAEL 76122

PCT

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference 55828	Date of mailing (day/month/year) 21 APR 2008
International application No. PCT/IL05/00849	International filing date (day/month/year) 08 August 2005 (08.08.2005)
Applicant SMART MEDICAL SYSTEMS, LTD.	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
1211 Geneva 20, Switzerland, Facsimile No.: (41-22) 338.82.70.

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.
3. ☐ With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:
- ☐ the protest together with the decision hereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
 - ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

Shortly after the expiration of 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within 19 months from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later); otherwise, the applicant must, within 20 months from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of 30 months (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Authorized officer Linda C.M. Dvorak <i>[Signature]</i> Telephone No. 703-308-2193 <i>[Signature]</i>
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Form PCT/ISA/220 (January 2004)

(See notes on accompanying sheet)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 55828	FOR FURTHER ACTION <small>see Form PCT/ISA/220 as well as, where applicable, item 5 below</small>	
International application No. PC1/L05/00849	International filing date (day/month/year) 08 August 2005 (08.08.2005)	(Earliest) Priority Date (day/month/year)
Applicant SMART MEDICAL SYSTEMS, LTD.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 2 sheets.

☐

It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the Report.

a. With regard to the language, the international search was carried out on the basis of:

☒

the international application in the language in which it was filed.

☐

a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

b. ☐

This international search report has been established taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91 Rule 43.6 bis(a)

c. ☐

With regard to any nucleotide and/or amino acid sequencedisclosed in the international application, see Box No. I.

2. ☐

Certain claims were found unsearchable(See Box No. II)

3. ☐

Unity of invention is lacking(See Box No. III)

4. ☐

With regard to the title,

☒

the text is approved as submitted by the applicant.

☐

the text has been established by this Authority to read as follows:

5. ☐

With regard to the abstract,

☒

the text is approved as submitted by the applicant.

☐

the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. ☐

With regard to the drawings,

a. the figure of the drawings to be published with the abstract is Figure No. 1

☒

as suggested by the applicant.

☐

as selected by this Authority, because the applicant failed to suggest a figure.

☐

as selected by this Authority, because this figure better characterizes the invention.

b. ☐

none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/IL05/00849

A. CLASSIFICATION OF SUBJECT MATTER

IPC: A61B 1/00 (2006.01)

USPC: 600/116

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 600/104, 115-116, 153; 604/96.01

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2004/0102681 A1 (Gross) 27 May 2004 (27.05.2004) entire document	1-16
X	US 4,862,874 A (Kellner) 5 September 1989 (5.9.1989) entire document	17-62
Y	US 5,025,778 A (Silverstein et al.) 25 June 1991 (25.06.91) entire document	17-51

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

* Special categories of cited documents:

"A"	document defining the general state of the art which is not considered to be of particular relevance	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"E"	earlier application or patent published on or after the international filing date	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O"	document referring to an oral disclosure, use, exhibition or other means	"Z"	document member of the same patent family
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search
03 April 2008 (03.04.2008)

Date of mailing of the international search report
21 APR 2008

Name and mailing address of the ISA/US
Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
Facsimile No. (571) 273-3201

Authorized officer

Linda C.M. Dvorak
Telephone No. 703-308-2193

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
SANFORD T. COLB
SANFORD T. COLB & CO.
P.O. BOX 2273
REHOVOT, ISRAEL 76122

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Applicant's or agent's file reference 55828		Date of mailing (day/month/year) 21 APR 2008
International application No. PCT/IL05/00849		International filing date (day/month/year) 08 August 2005 (08.08.2005)
International Patent Classification (IPC) or both national classification and IPC IPC: A61B 1/00(2006.01) USPC: 600/116		
Applicant SMART MEDICAL SYSTEMS, LTD.		

1. This opinion contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|--|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the opinion |
| <input type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Date of completion of this opinion 03 April 2008 (03.04.2008)	Authorized officer Linda C.M. Dvorak Telephone No. 703-308-2193
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Form PCT/ISA/237 (cover sheet) (April 2007)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/IL05/00849

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed
 - ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
2. ☐ This opinion has been established taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))
3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, this opinion has been established on the basis of:
 - a. type of material
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material
 - ☐ on paper
 - ☐ in electronic form
 - c. time of filing/furnishing
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in electronic form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/IL05/00849

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Claims NONE

YES

Claims 1-16, 52-62

NO

Inventive step (IS)

Claims NONE

YES

Claims 1-62

NO

Industrial applicability (IA)

Claims 1-62

YES

Claims NONE

NO

2. Citations and explanations:

Please See Continuation Sheet

Claims 1-62 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/IL05/00849

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

V. 2. Citations and Explanations:

Claims 1-16 lack novelty under PCT Article 33(2) as being anticipated by U.S. Patent Application Publication No. 2004/0102681 to Gross.

In regard to claims 1 and 12, Gross disclose an apparatus for fluid supply to the interior of a portion of a tubular body portion comprising: at least one first selectably extendible tubular body portion sealing element 12 adapted to be located at a first location along a length of the tubular body portion and at least one second selectably extendible tubular body portion sealing element 14 adapted to be located at a second location along the length, the at least one first selectably extendible tubular body portion sealing element and the at least one second selectably extendible tubular body portion sealing element being adapted to define, an intermediate region 20 of the length of the tubular body portion therebetween; a controller adapted for selectably sealing the at least one first and second tubular body portion sealing elements to the tubular body portion; and fluid supply functionality adapted for supplying a fluid to the intermediate region (see Figs. 1-2 and paragraph 0026).

In regard to claim 2, Gross disclose an apparatus for fluid supply to the interior of a portion of a tubular body portion further comprising an endoscope 32 at least partially extending along the tubular body portion (see Fig. 1b and paragraph 0025).

In regard to claim 3, Gross disclose an apparatus for fluid supply to the interior of a portion of a tubular body portion, wherein the at least one first and second tubular body portion sealing elements are movable relative to each other along the length (see Figs. 1-d-g and paragraphs 0022-0024).

In regard to claims 4-7, Gross disclose an apparatus for fluid supply to the interior of a portion of a tubular body portion, wherein at least one of the at least one first and second tubular body portion sealing elements comprises a selectably inflatable balloon (see Figs. 1d-g and paragraphs 0022-0024).

In regard to claims 8-10, 13-14, Gross disclose an apparatus for fluid supply to the interior of a portion of a tubular body portion, wherein at least one of the at least one first and second tubular body portion sealing elements is mounted on a distal portion of the endoscope (see Fig. 1c).

In regard to claim 11, Gross disclose an apparatus for fluid supply to the interior of a portion of a tubular body portion, wherein the fluid supply functionality employs an instrument channel of the endoscope (see Fig. 1c).

In regard to claim 15, Gross disclose an apparatus for fluid supply to the interior of a portion of a tubular body portion, wherein the fluid is air (See paragraph 0024).

In regard to claim 16, Gross disclose an apparatus for fluid supply to the interior of a portion of a tubular body portion, wherein the fluid supply functionality is adapted to inflate the intermediate region of the tubular body portion (see

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/IL05/00849

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Fig. 1a).

Claims 52-62 lack novelty under PCT Article 33(2) as being anticipated by U.S. Patent No. 4,862,874 to Kellner. In regard to claims 52, 54, Kellner discloses an apparatus for medical interaction with a tubular body portion comprising: at least one tube 1 comprising at least first 11 and second 15 lumens; a forward selectably inflatable balloon 13 in fluid communication with the first lumen, the forward selectably inflatable balloon being adapted to engage the tubular body portion when inflated; a controller being adapted for selectably inflating the forward selectably inflatable balloon; and an accessory which is insertable through the second lumen to a location rearward of the forward selectably inflatable balloon (see Figs. 1-4 and Col. 2, Lines 20-67).

In regard to claim 53, Kellner discloses an apparatus for medical interaction with a tubular body portion, wherein the at least one tube comprises an endoscope 8 (see Fig. 1).

In regard to claim 55, Kellner discloses an apparatus for medical interaction with a tubular body portion, also comprising an external tube through which slidably extends one of the at least one tube which defines the first lumen (see Figs. 1 and 3).

In regard to claims 56-57, 59-60, Kellner discloses an apparatus for medical interaction with a tubular body, wherein the at least one tube comprises an endoscope and an external tube and a balloon inflation tube defining the first lumen which slidably extends through the external tube (see Figs. 1-4 and Col. 2, Lines 20-67).

In regard to claims 58, 61, Kellner discloses an apparatus for medical interaction with a tubular body portion, wherein the rear selectably inflatable balloon is an anchoring balloon (see Figs. 1 and 3).

In regard to claims 52, 54, Kellner discloses an apparatus for medical interaction with a tubular body portion, wherein the rear selectably inflatable balloon is peripherally mounted on a distal portion of an endoscope (see Figs. 1-4).

Claims 17-51 lack novelty under PCT Article 33(3) as being obvious by U.S. Patent No. 4,862,874 to Kellner in view of U.S. Patent No. 5,025,778 to Silverstein et al.

In regard to claims 17, 24-25, 27, 32-40, Kellner discloses an endoscope assembly comprising: an endoscope 1; a working channel 11 defining at least one lumen; and an endoscope tool 12 adapted to travel through the at least one lumen of the external tube, the endoscope tool including a selectably inflatable balloon 13 (see Fig. 1 and Col. 2, Lines 20-67). Silverstein et al. teach of an analogous apparatus having a flexible tubing 54 which extends alongside the endoscope 30 (see Figs. 1-21 and 14-15). It would have been obvious to one skilled in the art at the time the invention was made to extend the working channel externally to the endoscope in the apparatus of Kellner to provide an endoscope having a smaller cross-sectional area during insertion and to provide more room within the endoscope channel itself as taught by Silverstein et al.

In regard to claims 18, 31, 42, 49, Kellner discloses an endoscope assembly, wherein the selectably inflatable balloon is an anchoring balloon (see Figs. 1 and 3).

In regard to claims 19-22, 26, 28, 43-45, 50-51, Kellner discloses an endoscope assembly, wherein the endoscope tool is inflatable forward the endoscope and bendable forward of the external tube (see Fig. 1 and Col. 2, Lines 20-67).

In regard to claim 23, Kellner discloses an endoscope assembly, also comprising a balloon inflation/deflation controller (see Fig. 1).

In regard to claims 29-30, Kellner discloses an endoscope assembly, wherein the inflatable balloon is mounted on the tube portion (see Fig. 1).

In regard to claims 41, 46-48, Kellner discloses an endoscope assembly, comprising a balloon inflation tube communicating with the selectably inflatable balloon (see Fig. 1).

NOTES TO FORM PCT/ISA/220 (continued)

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- (i) the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers, claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
2. [Where originally there were 15 claims and after amendment of all claims there are 11]:
"Claims 1 to 15 replaced by amended claims 1 to 11."
3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."
4. [Where various kinds of amendments are made]:
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

"Statement under Article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international application is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments and any accompanying statement, under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the time of filing the amendments (and any statement) with the International Bureau, also file with the International Preliminary Examining Authority a copy of such amendments (and of any statement) and, where required, a translation of such amendments for the procedure before that Authority (see Rules 55.3(a) and 62.2, first sentence). For further information, see the Notes to the demand form (PCT/IPEA/401).

If a demand for international preliminary examination is made, the written opinion of the International Searching Authority will, except in certain cases where the International Preliminary Examining Authority did not act as International Searching Authority and where it has notified the International Bureau under Rule 66.1bis(b), be considered to be a written opinion of the International Preliminary Examining Authority. If a demand is made, the applicant may submit to the International Preliminary Examining Authority a reply to the written opinion together, where appropriate, with amendments before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later (Rule 43bis.1(c)).

Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see the *PCT Applicant's Guide*, Volume II.